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KISHORE, G

EXAMINER

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1502

ART UNIT

PAPER NUMBER

7

02/12/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 1-21-92 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice re Patent Drawing, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, Form PTO-152
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

1. ☒ Claims 1-8, 10-14 are pending in the application.

Of the above, claims 3-5 are withdrawn from consideration.

2. ☒ Claims 9 have been cancelled.

3. ☐ Claims are allowed.

4. ☒ Claims 1, 2, 6-8, 10-14 are rejected.

5. ☐ Claims are objected to.

6. ☐ Claims are subject to restriction or election requirement.

7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed , has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. ; filed on .

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

Art Unit 1502

Applicants' request for the extension of time and the amendment filed in papers 5 and 6 are acknowledged filed in papers 5 and 6 are acknowledged. applicants election without traverse of composition and species 1 (dicarboxylic and salts, non-reducing sugar) in claims 1, 2, 6-8 and 10 and addition of claims 11-14 are also noted.

Upon consideration and in view of applicants' amendment of the claims, the 112 objections and rejections as set forth in pages 2-5 are withdrawn.

Claims 1, 2, 6-8 and 10-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites dicarboxylic acid salt; citric and isocitric acids are not dicarboxylic acids. The terms "prevent" or "delay" do not have the same meanings and thus, these terms render claim 1 indefinite.

"Another gonadotropin" in claims 7 and 10 is indefinite. does this term refer to the sources? For e.g. bovine, human etc.

This should be clarified in the claim.

"said non-reducing sugar" in claim 13 has no antecedent basis.

Claims 1, 2, 6-8, and 10-14 are rejected under 35 U.S.C. § 103 as being unpatentable over Kawaguchi et al. or Hamilton et

al.

Applicants argue that Kawaguchi et al. teach other compounds also as stabilizers and do not teach the criticality of a dicarboxylic acid salt. This is not persuasive since a finding that one of the protein stabilizers taught by the prior art is better suited for the instant protein does not constitute unexpected and unobvious results. These are manipulations practiced by an artisan in the highly developed field of biochemistry.

Applicants argue that Hamilton teaches choline derivatives and not dicarboxylic acid salts. This reasoning is not clear to the examiner. Hamilton's choline bitartrate is a choline salt of tartaric acid. Applicants further argue that Hamilton does not teach freeze dried composition; but from the very fact that Hamilton teaches that non-reducing sugars and salts are able to stabilize growth hormone either in dry mixture form (where there are no intimate interactions between the additives and the protein) and a solution form (where there is intimate interaction) an artisan could safely come to the conclusion that the composition can be lyophilized. The examiner would also like to point out that the most common procedure for removing the liquid medium after protein isolation is lyophilization. In the absence of evidence to the contrary, one could certainly assume that Hamilton's dry hormone is in fact obtained by lyophilization.

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The instant limitation in claim 11 is to be taught in lines 12-14, col. 2 of Kawaguchi. "trehalose" is deemed to be included in non-reducing sugar taught by Hamilton. Glutamate is taught by Hamilton on col. 2, line 20-22. The criticality of the limitation of claim 14 is unclear in the absence of comparative studies.

Claim 13 is rejected under 35 U.S.C. § 103 as being unpatentable over Kawaguchi and Hamilton as applied to claims 1, 2, 6-8 and 10-14 above, and further in view of Hayashi et al. or Iwasa et al. or Block et al..

Hayashi et al. disclose that trehalose stabilizes TNF compositions. (Note the abstract)

Iwasa et al. teach that trehalose stabilizes hCG-Beat-GAL compositions (note the abstract; col. 11, lines 65-col. 12, line 61).

Block et al. disclose that trehalose stabilizes the immunoconjugate against hCG (Note col. 5, line 3-col. 8, line 32)

Thus, to include the specific non-reducing sugar, trehalose in the teachings of Kawaguchi and Hamilton would have been obvious to an artisan since the above references teach that trehalose is the commonly used stabilizer.

In view of applicants' non-election of claims 3-5, the 103 rejection of said claims over Yashushi or Hivao is withdrawn. However, this will be reinstated if necessary.

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The reference os Koyama which teaches a stabilized hCG composition is cited if interest.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to G.S. Kishore at telephone number (703) 308-2440.

LSH
Kishore:css
February 11, 1992

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
ART UNIT 152